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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/016,159	01/30/1998	JONG Y. LEE	07004-002004	6621

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	38

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File copy

Office Action Summary

Application No.	Applicant(s)
09/016,159	JONG Y. LEE
Examiner	**Art Unit**
Fozia Hamud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 11, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above, claim(s) *1, 2, and 7* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *3-6 and 8-10* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Receipt of Applicants' arguments and amendments filed in Paper No.36, on 20 December 2002 is acknowledged. Claims 3-6 and 8-10 have been amended.

Claims 1-10 are pending. Claims 1, 2, and 7 are withdrawn from consideration by the Examiner as they are drawn to non-elected inventions. Thus, claims 3-6 and 8-10 are under consideration by the Examiner.

2. The following previous rejections and objections are withdrawn in light of Applicants amendments filed in Paper No.36, 12/20/02:

(I) The objection to claims 3-6 and 8-10.

(II) The rejection of claims 3 and 5 under the judicially created doctrine of obviousness-type double patenting.

(III) The rejection of claims 3, 5 made under 35 U.S.C. §102(b) as being anticipated by Harris et al. (JBC, 1992).

(IV) The rejection of claims 4, 6 and 10 made under 35 U.S.C. §102(a) as being anticipated by Elliot et al (JBC 1996).

(V) The rejection of claims 4, 6, 8, 9, 10 made under 35 U.S.C. §103 as being unpatentable over D'Andrea, (U.s. Patent 5,378,808).

3 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Applicants mention a declaration filed by inventor for Application 08/850,293, however, said declaration has not been submitted for the instant case, and therefore, it has not been considered by the Examiner.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 3-6 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide consisting of amino acid 25 to 250 of the full length human erythropoietin receptor, said polypeptide having specific affinity for human EPO with a molecular weight of 29 kDa, and an antibody that binds to said polypeptide and compositions comprising said polypeptide and antibody, respectively, does not reasonably provide enablement for "all" polypeptides having a specific affinity for human erythropoietin with a molecular weight of 29 kDa and all antibodies that binds to said polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

With respect to claims 3 and 4 which recite "a polypeptide consisting of human EPO receptor extracelluar domain" and "..an antibody that binds...", what is claimed in the instant invention broadly encompasses "all" polypeptides that have affinity for human EPO with molecular weight of 29 kDa and antibodies that bind to said . While the specification discloses that the purified protein consists of amino acid 25 to 250 of the full length of the human erythropoietin, has a molecular

weight of 29 kDa and that it binds to human EPO, (see page 5, line 4 through page 6, line 9, and page 23, line 20).

Claim 3 is a single means claim (M.P.E.P. 2164.08(a)). In In re Hyatt, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983), the Courts have held that: "A single means claim, i.e. where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph." (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor). Since no material limitations for the polypeptide consisting extracellular domain of EPO receptor have been recited in the claim, the claim encompasses every conceivable structure (means) for achieving the stated property (result), a fact situation comparable to Hyatt. The claimed invention encompasses polypeptides not envisioned or described in the specification, and neither does the specification disclose how these claimed nucleic acids can be distinguished from each other. The specification only enables an isolated polypeptide having specific structure, characteristics and properties. These properties may differ structurally, chemically and physically from other known proteins. The criteria set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue extermination. in the instant

application, the quantity of experimentation to determine which polypeptides and antibodies, are encompassed by the scope of the claims is practically infinite and the guidance provided in the specification very little. Therefore, it would require undue experimentation to determine which polypeptides having the desired biological activity, would be encompassed by the scope of the claim.

Furthermore, the amount of embodiments corresponding to the desirable polypeptides, may be innumerable and the enabled embodiments amount to only the polypeptide consisting of amino acid 25 to 250 of the full length human EPO receptor, said polypeptide having specific affinity for human EPO, also having a molecular weight of 29 kDa and antibodies that bind to said polypeptide. Therefore, there are substantial scientific reasons to doubt the scope of enablement, as set forth above.

Claim Rejections - 35 U.S.C. § 103

6. Claim 3 is rejected under 35 U.S.C. §103 as being unpatentable over Harris et al. (JBC, 1992)

Harris teaches a fusion protein that consists of an upstream portion (glutathione-transferase), a cleavage site and the extracellular domain of EPO receptor, and purifies said fusion protein. Harris et al also describe the immobilization of the extracelluar domain of EPO receptor on glutathione-agarose beads.

However, Harris et al do not teach a polypeptide consisting of only the extracellular domain of human EPO receptor.

Sambrook et al teach the cloning of cDNA encoding specific proteins and transfection of host cells with recombinant expression vectors to express and produce desired proteins. (Pages 16.3, 16.17-16.18 and 16.30-16.31).

Therefore, It would have been prima facie obvious at the time of the invention to to produce an isolated polypeptide consisting of only the extracellular domain of EPO receptor, by genetically engineering expression systems that incorporate cDNA that encodes only the extracelluar domain of human EPO receptor, using the methods thought by Sambrook et al, because, Harris et al teach that the extracelluar domain of human EPO receptor may be useful in developing receptor based assays for physiologic and functional studies of the EPO receptor.

Conclusion:

7. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Thursday from 6:30AM to 4:00PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
07 April 2003

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